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Delaware reaches consumer protection settlement with Pfizer

Wilmington, DE – The Delaware Attorney General's office announced today that it has reached a nationwide settlement with Pfizer Inc. following a 4 month investigation into the drug company's alleged improper marketing of the antipsychotic drug Geodon. In a complaint soon to be filed in Superior Court along with the settlement agreement, Delaware alleges that Pfizer engaged in unfair and deceptive practices when it marketed Geodon for off-label uses. As a result of the investigation, Pfizer has agreed to change how it markets Geodon and will not promote off-label uses. Pfizer will also pay $33 million to the 43 states that participated in the investigation. The Delaware Consumer Protection Fund will receive $448,200.

Delaware and Maryland led the states' negotiation of the settlement of Pfizer's marketing and promotional practices. Deputy Attorney General Ian McConnel, Director of the Consumer Protection Unit, handled the case for Delaware.

"This case demonstrates that we are actively monitoring the pharmaceutical industry for inappropriate and illegal sales and marketing practices and are holding it accountable," stated Timothy Mullaney, Director of the Attorney General's Fraud and Consumer Protection Division. "Delaware's Consumer Protection Unit took a leading role in this nationwide investigation and we'll continue to be out front in protecting Delaware consumers and enforcing fair business practices."

Geodon is the brand name for the prescription drug ziprasidone, which is approved by the U.S. Food and Drug Administration (FDA) for treatment of schizophrenia and for certain symptoms of bipolar disorder in adults. The states' complaint alleges that Pfizer promoted Geodon for off-label uses, which are uses that have not been approved by the FDA, including pediatric use and use at higher than FDA-approved dosages. Although a physician is allowed to prescribe drugs for off-label uses, federal law prohibits pharmaceutical manufacturers from marketing their products for off-label uses.

Under terms of the settlement, Pfizer will:

- Not make false, misleading or deceptive claims regarding Geodon or promote it for off-label uses
- Not promote Geodon using selected symptoms of the FDA-approved diagnoses unless certain disclosures are made regarding the approved diagnoses
- Post on its website a list of physicians and related entities who received payments from Pfizer until 2014
- Provide product samples of Geodon only to health care providers who have specialties that customarily treat patients who have diseases for which treatment with Geodon would be consistent with its current labeling

- Register and post on a publicly accessible website certain Pfizer-sponsored clinical trials
- Require its medical staff to be responsible for the identification, selection, approval and dissemination of scientific article reprints containing off-label information regarding Geodon, and that such information not be referred to or used in a promotional manner.

The settlement also requires that for a nine-year period (which extends beyond the patent term for Geodon), Pfizer will require its medical staff, rather than its marketing staff, to be responsible for developing and approving the medical content for all medical letters regarding Geodon.

In addition, for a six-year period, Pfizer must:

- Disclose on its website information about grants it makes to health care providers, including continued medical education (CME) grants
- Not use grants to promote Geodon, or condition CME funding on Pfizer's approval of speakers or program content
- Contractually require continuing medical education providers to disclose Pfizer's financial support of their programs and any financial relationship with faculty and speakers

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